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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,371	03/28/2001	Kohji Egawa	31508	4334

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EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/819,371

Applicant(s)

EGAWA, KOHJI

Examiner

Karen A Canella

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 39-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____  | 6) <input type="checkbox"/> Other: ____                                     |

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### **DETAILED ACTION**

Claims 34-36 have been canceled. Claims 39-59 have been added.

Sections of Title 35, U.S. Code not found in this action can be found in a previous action.

Claim 39 is objected to for the typographical error of "cancer call" rather than "cancer cell".

Claims 39-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39 and 50 fail to link the outcome of detecting the immune complex with the diagnosis of cancer as indicated in the final method step and the method preamble.

Claim 59 fails to link the detection of the HLA-F antibody with the diagnosis of cancer as recited in the method preamble.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A) As drawn to new matter

Claim 50 is drawn to a method of diagnosing a nonspecific cancer comprising applying a known amount of a cancer cell specific antigen and a labeled anti-HLA-F antibody to a body fluid. The specification provides a written description of only a HLA-H antigen and not the more broadly claimed cancer cell antigen, which would read on generic cancer antigens such as

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alpha-feto protein and CEA. One of skill in the art would reasonably conclude that applicant was not in possession of the claimed invention.

(B) As drawn to inadequate written description

Method claims 39-59 are dependent upon the identity of the "cancer cell specific" HLA-H antigen. The specification describes the cancer cell specific antigen as "any antigen" as long as it binds to an anti-HLA-F antibody in body fluid (page 6, line 20 to page 7, line 1). However, this qualification does not represent a limiting definition because the anti-HLA-F antibody would be dependent upon the structure of the HLA-F antigen. The specification cites SEQ ID NO:5 and SEQ ID NO:6 as preferred embodiments but also states that the HLA-F antigen may be part or an entirety of said SEQ ID NO (page 7, lines 6-9). It is noted that a "part" of an amino acid sequence need only be a single amino acid, therefore a polypeptide need only have a single amino acid in common with SEQ ID NO:5 or 6 to fulfill the specific embodiment of a part or SEQ ID NO:5 or 6. Thus the claims are thus dependent upon a genus of HLA-F antigens which are highly variant. The description of SEQ ID NO:5 and 6 fails to describe this claimed genus because the genus tolerates members which differ substantially in structure from the instant SEQ ID NO:5 and 6. One of skill in the art would reasonably conclude that applicant was not in possession of the claimed genus of HLA-F antigens and accordingly the DNA encoding the HLA-F antigens. Because applicant was not in possession of the claimed genus of products, it follows that applicant was not in possession of the methods reliant on said claimed genus.

All other rejections and objections as set forth in the previous Office action are withdrawn in light of applicant's amendments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828.

The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.  
12/27/2004

*Karen A. Canella*  
KAREN A. CANELLA PH.D.  
PRIMARY EXAMINER